NWX-HHS FDA

Moderator: Jeff Ventura
January 5, 2011
10:00 am CT

Coordinator: Welcome and thank you for standing by. All participants will be in a listen-only mode until the question and answer session of today's conference call. At that time please press star 1 on your touchtone phone. Today's call is being recorded, if anyone has any objections you may disconnect at this time.

I would like to introduce your host for today's call, Mr. Jeff Ventura. Sir, you may begin.

Jeff Ventura: Thank you, (Diane). Good afternoon and thank you for participating in today's call. My name is Jeff Ventura from the FDA's Office of Public Affairs. This is a media briefing to announce the FDA's requirement of substantial equivalence reviews for new tobacco products.

I'm joined today by the Director of the FDA's Center for Tobacco Products, Dr. Lawrence Deyton. Joining Dr. Deyton is Dr. David Ashley who is the Director of the Office of Science at the Center, Ann Simoneau who heads up the Center's Office of Compliance and Enforcement and (Kristy Stark) who is a Senior Regulatory Health Project Manager at the Center.

Three of our speakers will make brief opening remarks. After their remarks we will move to the question and answer portion of the call. Our speakers will be available to answer any questions at that time. Reporters will be in a listen-only mode until we open the call up for questions.

When asking your question we ask that you please remember to state your name and affiliation. Also please limit yourself to one question and one follow up so we can get to as many questions as possible.

The news release for this announcement has been sent to reporters on both the Center for Tobacco Products and FDA media lists, distributed on the PR News Wire and has been posted on the FDA's Website at www.fda.gov.

I will now turn the call over to Dr. Deyton for his opening remarks.

Dr. Lawrence Deyton: Thank you very much. And I want to thank everybody for joining the call. As you know today we've issued several documents related to the substantial equivalence provisions of the Family Smoking Prevention and Tobacco Control Act.

These substantial equivalence provisions required by the Tobacco Control Act are meant to ensure that new tobacco products or changes to existing products are evaluated by the FDA before they enter the marketplace and are consumed by millions of people.

The law requires this because up until now tobacco products have been the only mass-consumed products for which users do not know what they're consuming and because manufacturers frequently alter ingredients again without anyone knowing what they're consuming.

This law requires FDA to carefully examine the impact of those changes or new products may have on the public health. No longer will changes to products consumed by millions of Americans be made without anyone knowing.

Specifically though the Tobacco Control Act allows marketing of products that are equivalent to those which were on the market on February 15, 2007. The law also requires those that are not equivalent to be prohibited from the market or withdrawn if they're already available if the changes raise different questions of public health.

The substantial equivalent requirements of the Tobacco Control Act is to assure that any new or changed tobacco product are not worse to the public health than those that were on the market February 15, 2007.

Now to assist industry in complying with these requirements of the Tobacco Control Act today FDA has issued a final guidance for industry. This guidance provides recommendations and information about the process industry can use to submit reports to the FDA as well as how FDA will review those submissions.

Information contained in the submissions tobacco companies will provide to the FDA will establish a scientific foundation about all the characteristics of these products; something that has never been publicly known to those outside the industry as well as how these products change over time.

Today FDA also has issued a proposed rule to establish procedures for requesting an exemption from the substantial equivalence requirements of the Tobacco Control Act. The proposed rule describes the process and criteria for

requesting an exemption and how - and explains how FDA would review requests for exemptions.

The substantial equivalence guidance FDA has published today will guide the tobacco industry on how to provide that important information for the scientific foundation needed to protect the public health as required by the Tobacco Control Act.

To discuss the scientific and the procedural aspects of the information the law requires manufacturers to submit I'd like to turn the call over to Dr. David Ashley. But before I do that I want to emphasize a very important feature of the law and of the FDA guidance that we've issued today.

The law requires tobacco manufacturers to submit this substantial equivalence information to the FDA by March 22, 2011. That is the law. FDA understands that this requirement is new for all tobacco manufacturers and the guidance we are issuing today gives them significant information on how they might meet the requirements of the law.

FDA understands that there may be the need for some time to review and understand these guidelines, to collect the information to be submitted and possibly to respond to FDA questions.

Thus it is our intent to allow manufacturers who have acted diligently in preparing their submissions a reasonable amount of time to supplement their initial report provided that these manufacturers submit their initial report by March 20 - by the March 22, 2011 deadline.

Now let me turn this over to Dr. Ashley who is Director of our Office of Science.

Dr. David Ashley: Thank you Dr. Deyton. As Dr. Deyton indicated substantial equivalence is one way given by the Tobacco Control Act for a manufacturer to introduce a new product into the market or to change a product that is already on the market.

This part of the law also provides FDA with authority to scientifically evaluate whether new or changed products raise new questions of public health. These determinations will be based on risks and benefits to the population as a whole including users and nonusers, a standard outlined in the Tobacco Control Act.

In addition manufacturers who are seeking a marketing authorization for their product by being shown to be substantially equivalent must also show that their product is in compliance with requirements of the Tobacco Control Act.

For a new product to be substantially equivalent it must be the same in terms of ingredients, design, composition, heating source and other characteristics to an existing single predicate product or if it has different characteristics they must not raise different questions of public health.

If a product does raise different questions of public health then FDA can find that the product is not substantially equivalent to a single predicate product that was on the market on February 15, 2007. If that is the case for a new product to be marketed it must attain authorization from FDA through a new tobacco product application.

The Tobacco Control Act contains a special provision for new tobacco products that were introduced into the market between February 15, 2007 and March 22, 2011. Manufacturers of these tobacco products must remove their products from the market unless they submit a report to FDA before March

23, 2011 intending to demonstrate that their product is substantially equivalent to a predicate tobacco product.

Manufacturers who submit these reports may continue to market their product unless FDA issues an order finding the product to be not substantially equivalent to the predicate product.

We understand that fully addressing the information in a substantial equivalence report will be a significant burden for some tobacco product manufacturers. But FDA is required to implement the provisions outlined in the federal law.

So for products which are already on the market FDA will work on a case by case basis with tobacco product manufacturers who submit substantial equivalence reports by the March 22, 2011 deadline and those that make a good faith effort in preparing their submissions to identify reasonable timelines for them to provide the remaining information necessary for FDA to make a determination.

And now Ann Simoneau, CTPs Director of Compliance and Enforcement, will explain enforcement of the substantial equivalence aspects of the law.

Ann Simoneau: Thank you Dr. Ashley. A tobacco product that was commercially marketed in the United States as of February 15, 2007 is not a new tobacco product, is not subject to the premarket requirements of the act. Manufacturers know when they commercial marketed their tobacco products in the US.

Information that manufacturers can refer to may include tobacco products dated advertisements, dated promotional materials, catalogues, manufacturing documents and any other documents that they may have.

A new tobacco product is defined in the act as a tobacco product that was not commercial marketed in the United States as of February 15, 2007 or any modification of a tobacco product where the modified product was commercially marketed in the United States after February 2007.

Manufacturers of new tobacco products must remove their products from the market unless they submit a report to FDA before February 23, 2011 intending to demonstrate that their product is substantially equivalent to a predicate tobacco product.

These manufacturers who submit their reports may continue to market their products unless FDA issues an order finding the product to not be substantially equivalent to the predicate product.

However manufacturers of new tobacco products who fail to submit a report to FDA before March 23, 2011 will be in violation of the FDA if they continue to market and sell their new tobacco product in the United States.

Jeff Ventura: Thank you very much, Ann. At this time we will begin the question and answer portion of the briefing. Operator, we'll take the first question please.

Coordinator: Thank you. If you would like to ask a question please press star 1 on your touchtone phone, please unmute your line so that we may announce you. One moment please. One moment for the first question.

Michael Felberbaum with the Associated Press, you may ask your question.

Michael Felberbaum: Hi, great, good morning everyone. Two quick questions. First can you explain - maybe I just missed it but what's the significance of the February 15, 2007 date?

And then the second question is as far as talking about what was commercially available before that date is it company specific or is it product specific in terms of let's say there's a product made by another company that is similar that was on the market before that date. Can a company - another company apply and say that their product is substantially equivalent to something commercially available by another company?

Dr. Lawrence Deyton: Michael, Lawrence Deyton, thank you for the questions and I'll take the first one. The significance of the February 15, 2007 date is that is the date that both the House and the Senate first introduced the Family Smoking Prevention and Tobacco Control Act for consideration.

And that date has remained part of the law and it is in the final law so that is where that comes from.

Michael Felberbaum: Okay.

Dr. Lawrence Deyton: In terms of the applicability of - well your second question I think I'll start with Dr. Ashley.

Dr. David Ashley: If the companies are able - the requirements to look at a predicate product is - I guess if I understand your question correctly is really product specific. So the companies must furnish the information that's needed so that FDA can determine whether the new product is substantially equivalent to the predicate product.

And it is not manufacturer specific. If the companies can provide that information that proves to FDA that those are substantially equivalent they can base a new product on a predicate product from the other manufacturer. But they must be able to furnish the information so that FDA can make a decision about substantial equivalence.

Michael Felberbaum: Okay great, thank you.

Jeff Ventura: Thank you Michael. (Diane), we'll take the next question please.

Coordinator: Jennifer Corbett with Wall Street Journal you may ask your question.

Jennifer Corbett: Yeah, hi. Thanks for taking my question. I have a couple questions actually. The first one is on the, again, sort of relating to the date. What is considered a new product? I mean, a lot of major cigarette brands and smokeless tobacco brands have been around for decades.

And how do you know if somebody went in and changed a product, you know, changed an ingredient in one of those products, you know, after that date? And if so does that make it a new product?

Dr. Lawrence Deyton: Yeah, thanks; that's a great question. Let me ask Ann Simoneau to again review for us the definition of a new tobacco product that is from the law.

Ann Simoneau: Sure. Thank you, Dr. Deyton. Under the law it's - a new tobacco product is defined as any tobacco product that was not commercially marketed in the US as of February 15, 2007 or any modification of an existing tobacco product where the modified product was commercially marketed in the US after February 15, 2007.

Dr. Lawrence Deyton:Does that answer your question, Jennifer?

Jennifer Corbett: Well so then if it's - the product was modified in such a way that it became a new product and the company has marketed it that way?

Ann Simoneau: Yes.

Jennifer Corbett: Okay, all right. And then the - I guess the other question I have - and it might be a little bit unrelated to this - is if companies have developed new products or they are developing new products and there's a company yesterday that said they have developed a new moist snuff tobacco product that they want to submit for agency approval.

I mean, is that going to be a separate pathway if you, you know, how do they prove that their product is equivalent to another product if it's - if they are considering it a new, quote, unquote, safer product?

Dr. Lawrence Deyton:Let me start with that and then ask my colleagues also to join in. So the information - the guidance that we've issued today is directly related to substantial equivalence.

There is - for new tobacco products there will be a different pathway for proposing new tobacco products particularly after the March 22, 2011. So the premarket tobacco product application provisions are in a separate part of the law, Section 9.10 of the law, that would govern something that is completely new.

Jennifer Corbett: Okay.

Dr. Lawrence Deyton: One thing that I think is important to emphasize about the guidance that we've issued today; this relates to those tobacco products for which the Tobacco Control Act gives FDA authority and that is cigarettes, smokeless tobacco and roll your own tobacco products.

Jennifer Corbett: Okay thank you.

Jeff Ventura: (Diane), we'll take the next question please.

Coordinator: Richard Craver with Winston Salem Journal you may ask your question.

Richard Craver: Thank you. I have a couple questions as well. First of all we reported back when the act - Tobacco Act was made into law back in June of 2009 that this was coming. Is this sort of a confirmation of what you all had provided in guidance back in June of 2009? And is there anything as far as implementation that is different from what you all said back in June 2009?

Dr. Lawrence Deyton: This is - if I understand your question, Richard, certainly, you know, since this became law in June 2009 this is not a surprise to any of us; we're just today articulating guidance to industry on how to implement sections of the law. So there's no news here in that sense other than the guidance gives industry much more detailed information about how they can comply with these parts of the law.

Richard Craver: Okay because that was one of the things I was trying to figure out because we had reported essentially what you announced today back in June of 2009. Is there any - back in June of 2009 did you all have any sense of what the penalties were going to be? Had you all made those known at that point?

Dr. Lawrence Deyton: The Tobacco Control Act does give FDA several enforcement authorities under the law, again no news there; it's all part of the original law. We certainly are anticipating industry to fully comply with these - these portions of the law.

This guidance gives them very detailed and concrete information about how they can comply. Ann, I don't know if there's anything else you want to say about penalties?

Ann Simoneau: Sure. You know, failure to comply with the substantial equivalence requirements under the act would render their product to be adulterated and (branded). And we have - Congress has given us the enforcement tools to bring enforcement actions; possible seizures, injunctions or other types of enforcement against any (violative) product that's in US commerce.

Richard Craver: So I guess in this sense that's when you're talking about modification does that include introducing a new flavor or does it have to be something substantial to the nature of the product itself?

Dr. Lawrence Deyton: Let me ask Dr. Ashley to respond to that.

Dr. David Ashley: The statute is fairly specific about exactly what constitutes a change in a product. And those things include the ingredients, the design, the composition, the heating source or other characteristics so it's a fairly broad definition of what a change constitutes.

Jeff Ventura: Richard, thank you for your question...

Richard Craver: Thank you.

Jeff Ventura: ...we're going to have to go onto the next one.

Richard Craver: Thank you.

Jeff Ventura: Thank you. (Diane) the next question please.

Coordinator: Lyndsey Layton of the Washington Post you may ask your question.

Lyndsey Layton: Hi, good morning. Thanks everyone. My question is I'm trying to get some sense of how - the universe of products that would be affected by this. And I'm wondering through your knowledge of the tobacco industry how many new products come on line in a given year or how many changes are made. Are we talking about a couple dozen or a couple hundred? I just - I really have no sense. That was my first question and I've got a follow up as well.

Dr. Lawrence Deyton: Okay. First of course it is the responsibility of industry to understand these requirements and to report to FDA about any new tobacco products or changes in their products. Let me ask Dr. Ashley to address this as much as we can in terms of specifics about what we think in terms of the number of products. Any sense, David?

Dr. David Ashley: It's very hard for us to get a sense on the exact number that are going to be submitted to us in the next three months and the next year. We have got some broad ideas about what that might be but we really won't know until the industry fully begins to respond to the guidance we've issued today and to the full parts of the law.

Lyndsey Layton: I understand that, Dr. Ashley but could you just give us a sense of what you're prepared for or what you, you know, the broad sense of what you're expecting just a rough gauge?

Dr. David Ashley: Again I can't really answer that question. We're prepared here to handle anything that comes. We're fully prepared to respond to what the industry submits to us. But it 's hard for us to say right now exactly what that number is going to be.

Dr. Lawrence Deyton: And, Lyndsey, we can get back to you with more specifics offline once we discuss this further.

Lyndsey Layton: That's great, Dr. Deyton. My follow up question if I may I just wanted to ask you in terms of the Center how staffed up you are. Are you - because I think one of the more recent briefings we've had, you know, you've been hiring and you've been putting people in position but I just wonder are you fully ready or you still have some more hiring to do? Can you give us just a sense of how well prepared you are at this point?

Dr. Lawrence Deyton: We are fully prepared to handle the - whatever we need to do to support industry and their submission of these documents and their compliance with the law. We have about 200 people on board at this point and we're ready to go.

Jeff Ventura: Thank you Lyndsey.

Lyndsey Layton: Thanks.

Jeff Ventura: (Diane) we're ready for the next question please.

Coordinator: Yes sir. Once again if you would like to ask a question please press star 1 on your touchtone phone. Daniel DeNoon with WebMD you may ask your question.

Daniel DeNoon: Thank you very much. The wording of this guidance talking about heating source and composition makes me think that maybe you have certain products in mind. Are there some products that you'll be keeping an eye on to see, make sure that industry files such as e-cigarettes or new brands of Snus?

Dr. Lawrence Deyton: Let me ask Dr. Ashley to elaborate after I start. But this provision relates directly to tobacco products for which FDA has jurisdiction which are cigarettes, roll your own and smokeless tobacco. And we will be looking at all submissions that come in.

Dr. David Ashley: I will add to what Dr. Deyton has just said. The wording - that wording that you just referred to is specifically wording that is in the statute so our guidance is referring directly to that wording. This is not wording that we came up with at CTP this is wording that's directly in the statute that came from Congress.

Daniel DeNoon: So would e-cigarettes for example or would e-cigarettes specifically be included among these products?

Dr. Lawrence Deyton: No.

Daniel DeNoon: Thank you.

Jeff Ventura: (Diane)...

((Crosstalk))

Jeff Ventura: Thank you.

Coordinator: (Heidi Sweet) with Elsevier Medical News you may ask your question.

(Heidi Sweet): Hi, thank you. I was just wondering whether one of you could just speak to what the implications might be for public health and is there a message for family physicians as far as what to make of this? I don't know what the affects might eventually be on possibly discouraging people from taking up smoking. Could you maybe speak to that a little bit?

Dr. Lawrence Deyton: Yeah, let me start and then let me ask my colleagues to chime in too. Again this is Dr. Deyton. I think the Tobacco Control Act is very clear that this is an important public health tool. And particularly the concept that for a long time, forever in fact, the ingredients of these products have not ever been known to those people who consume them.

And so the law does require FDA now to carefully examine these products and any changes that tobacco manufacturers may want to make or new products. And so in that sense that the concept that these products being consumed by millions of people now FDA has a responsibility to look at the overall public impact of any changes or new products and particularly if those changes might raise new questions of public health.

And so I think for the family practitioner that you talked about that physician now knows that FDA at least is looking and that industry is required to submit this information to the FDA.

Dr. David Ashley: Just - I just want to add - this is David Ashley - I just want to add a little bit to that and what Dr. Deyton said is exactly right. The standard that we work under here in the Center for Tobacco Products is a public health standard. And so that is at the center of all the decisions we're making.

So as we are reviewing these products and evaluating whether to issue a marketing authorization that will be at the forefront of all our decisions. And so we will be looking at the possible impact on users and nonusers.

Dr. Lawrence Deyton: I think one thing to elaborate FDA's involvement in this role does not indicate that these products are safe; there are no tobacco products that are safe. The Tobacco Control Act requires FDA to evaluate substantial equivalence, as we've discussed in the last couple of minutes, with that looking for questions - different public health questions in mind.

Jeff Ventura: Thank you, doctor. (Diane), we'll take the next question please.

Coordinator: Susan Heavey with Reuters you may ask your question.

Susan Heavey: Thank you so much. Most of my questions have been answered but in terms of staffing how much more staff do you plan to hire or are you pretty much done at this point?

Dr. Lawrence Deyton: No we're not done hiring staff in fact each of the six offices within the Center for Tobacco Products continues to staff up. And so I expect the number of employees to continue to grow for a period of time. You know that the Center for Tobacco Products has been existence for just a little more than a year.

I think the very important question from before still is - I want to reiterate the answer - we have sufficient staff and support to work with industry in terms of reviewing their substantial equivalence reports as they come in. So I think any concern about throughput issue I want to put to rest.

Jeff Ventura: (Diane), we'll take another question.

Coordinator: Rebecca Adams from Congressional Quarterly you may ask your question.

Rebecca Adams: Yes, thank you. And again a lot of my questions have been answered. But I wanted to get a better sense of some of the resources that will be devoted to investigating the claims of the companies. How would you be able to know - will you have investigators actually checking out whether a company has made a change that they are not reporting to you?

And I also wondered could this somehow discourage a company from making a change that could improve public health or the safety of their products?

Dr. Lawrence Deyton: Let me start and then ask my colleagues, David Ashley and Ann Simoneau to chime in too. In terms of - we're certainly anticipating that tobacco manufacturers that submit reports their reports will be true and accurate; that is the law.

We do have multiple sources of information by which we will be checking what they're submitting. And as Ann Simoneau has already said Congress has given FDA several enforcement authorities if we suspect that in fact there has been untruthful submissions made.

Ann Simoneau: Yeah and we expect manufacturers to comply with the substantial equivalence requirements. And - however we will be doing ongoing and continued surveillance to ensure that companies are in compliance and have submitted the required documents to the Office of Science for review for substantial equivalence determination.

Rebecca Adams: Okay.

Jeff Ventura: Thank you.

Rebecca Adams: And is there any concern - is there any concern at all that a company might not make a change that they believe would result in a safer product?

Dr. Lawrence Deyton: Oh it certainly, you know, I think that the concept of innovation and improving products is something that I would - I think the substantial equivalence provisions actually only encourages.

Rebecca Adams: Okay.

Dr. Lawrence Deyton: So I don't see any problem there.

Rebecca Adams: Okay.

Jeff Ventura: Thank you. (Diane), we have time for two more questions.

Coordinator: John Blackwell from the Richmond Times Dispatch you may ask your question.

John Blackwell: Yes thanks for taking these questions; most of mine have been answered as well. But I wonder if you might, just to clarify, talk a little bit about the difference between these requirements today and the modified risk pathway and what - how the standards would be different?

Dr. Lawrence Deyton: Yeah, let me ask Dr. Ashley to help us there.

Dr. David Ashley: We're not prepared at this point to go into a lot of detail on modified risk; that guidance is being developed. The description and explanation is in the statute and that's what we're working off.

But I will say one thing just for clarification substantial equivalence is focused primarily on changes to the product or introduction of new products. Modified risk is focused on claims being made by the manufacturer on a change in risk. So they are two very complementary parts of the statute.

Jeff Ventura: Thank you, doctor. (Diane), we'll take our final question.

Coordinator: Our final question comes from Malcolm Spicer with Elsevier; you may ask your question.

Malcolm Spicer: Yes thank you. My question actually is on modified risk also. I'm not sure from what was just stated as far as how the - how this item today affects how the agency will review or consider claims for modified risk.

Dr. Lawrence Deyton: They're different pathways I think is the major issue is that substantial equivalence is one, for products that are either already on the market or new. Modified risk is a completely separate set of - separate section sets, separate set of criteria so industry has multiple options.

Malcolm Spicer: So then this today does not affect what the agency will do with modified risk claims?

Dr. Lawrence Deyton: I think that this...

Dr. David Ashley: What we've - this guidance we put out today does not address modified risk claims; that is a separate guidance and will be coming out at a later time.

Malcolm Spicer: Very good, thanks very much.

Jeff Ventura: Okay this concludes today's media briefing. Thank you, folks. A replay will be available in about an hour and will be available for 30 days thereafter. Thank you for your participation. Have a good day.

Coordinator: Thank you for your participation. The call has ended; you may disconnect at this time.

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